

In the Claims

1. (currently amended) A computer-implemented method of simulating the corneal strain relationship produced by patient specific corneal deformation in response to a ~~physical~~ an insertion of an insert in the cornea, comprising the steps of:

(a) measuring the topography of a portion of the patient's eye using a topography measuring device to produce patient specific x, y, z coordinates for a number of patient specific data points of the surface of the patient's eye;

(b) storing in a storage device a mathematical analysis model of the patient's eye, the model including a number of nodes, the connectivities of which define a plurality of elements;

(c) determining a value representing intraocular pressure in the patient's eye and assigning a strain value to each element;

(d) representing ~~a physical insertion~~ an insertion of an insert in the cornea, and thus a region of increased stiffness in the cornea, in the mathematical analysis model by assigning new values to the topography of the portion of the patient's eye surrounding the ~~insertion~~ insert

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corresponding to the size, shape, and thickness of the ~~insertion~~ insert and a value of the modulus of elasticity to elements surrounding the ~~insertion~~ insert computed from the value determined in step (c); and

(e) using the mathematical analysis model to compute new values of the patient specific x, y, z coordinates and therefrom, new strain relationships resulting from the ~~physical-insertion~~ insertion of the insert in the cornea at each of the nodes, respectively.

2. (currently amended) A computer-implemented method of simulating the corneal strain relationship produced by patient specific corneal deformation in response to a ~~physical~~ an insertion of an insert in the cornea, comprising the steps of:

(a) measuring the topography of a portion of the patient's eye using a topography measuring device to produce patient specific x, y, z coordinates for a large number of patient specific data points of the surface of the patient's eye;

(b) storing in a storage device operably associated with a computer system for implementing the computer-implemented method, a mathematical analysis model of the patient's eye, the model including a number of nodes, the

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connectivities of which define a plurality of elements;

(c) determining a value representing intraocular pressure in the patient's eye and assigning a strain value to each element;

(d) representing ~~a physical insertion~~ an insertion of an insert in the cornea, and thus a region of increased stiffness in the cornea, in the mathematical analysis model by changing the z coordinate of the nodes surrounding the ~~insertion~~ insert and representing the effect of the ~~physical insertion~~ insert by means of a plurality of nonlinear spring elements each connecting an insertion-bounding node to an adjacent node, respectively each of the plurality of nonlinear spring elements having a load deflection curve based upon size, shape, and thickness of the ~~insertion~~ insert and the value obtained from step (c); and

(e) using the mathematical analysis model to compute new values of the patient specific x, y, z coordinates and therefrom, new strain relationships resulting from the ~~physical insertion~~ insertion of the insert in the cornea at each of the nodes, respectively.

3. (currently amended) The computer-implemented method of claim 2 including establishing at least one

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vision objective for the patient's eye, wherein step (e) includes comparing the simulated strain relationship within the cornea with a vision objective to determine if the ~~physical insertion~~ insertion of the insert in the cornea results in the vision objective being met, and, if the vision objective is not met, modifying the ~~physical insertion~~ insertion of the insert in the cornea and/or adding another changes to the cornea in the mathematical analysis model and repeating step (e) to determine if the at least one vision objective is met.

4. (currently amended) A computer-implemented method of simulating the corneal strain relationship produced by patient specific corneal deformation in response to a ~~physical insertion~~ an insertion of an insert in the cornea, comprising the steps of:

(a) measuring the topography of a portion of the patient's eye using a topography measuring device to produce patient specific x, y, z coordinates for a number of patient specific data points of the surface of the patient's eye;

(b) storing in a storage device a mathematical analysis model of the patient's eye, the model including a predetermined number of nodes, the connectivities of which

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define a plurality of elements;

(c) determining a value representing intraocular pressure in the patient's eye and assigning a strain value to each element;

(d) representing a ~~physical~~ an insertion of an insert in the cornea, and thus a region of increased stiffness in the cornea, in the mathematical analysis model by assigning at least one of reduced values of the thickness and a reduced value of the modulus of elasticity to elements corresponding to the ~~physical~~ insertion of the insert in the cornea; and

(e) using the mathematical analysis model to compute new values of the patient specific x, y, z coordinates and therefrom, new strain relationships resulting from the ~~physical~~ insertion of the insert in the cornea at each of the nodes, respectively.

5. (currently amended) The computer-implemented method of claim 4 including establishing at least one vision objective for the patient's eye, wherein step (e) includes comparing the simulated deformation of the cornea with the vision objective to determine if the ~~physical~~ insertion of the insert in the cornea results in the vision objective being met, and, if the vision objective is not

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met, modifying the ~~physical~~ insertion of the insert in the cornea in the mathematical analysis model and repeating step (e) to determine if the at least one vision objective is met.

6. (currently amended) A computer-implemented method of simulating the corneal strain relationship produced by patient specific corneal deformation in response to a ~~physical~~ an insertion of an insert in the cornea, comprising the steps of:

(a) measuring the topography of at least a portion of the patient's eye using a topography measuring device to produce patient specific x, y, z coordinates for each of a plurality of patient specific data points of a surface of the patient's eye;

(b) storing in a storage device associated with the computer system a finite element analysis model of the patient's eye, the finite element analysis model including a number of nodes, the connectivities of which define a plurality of elements;

(c) operating a processing device which interfaces with the storage device to interpolate between and extrapolate beyond the patient specific data points to obtain a reduced number of patient specific x, y, z

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coordinates that correspond to nodes of the finite element analysis model, respectively, and assigning the reduced number of patient specific x, y, z coordinates to the various nodes, respectively;

(d) determining a value representing intraocular pressure in the patient's eye and assigning a strain value to each element;

(e) representing a first ~~physical~~ insertion of an insert in the cornea, and thus a region of increased stiffness in the cornea, in the finite element analysis model by representing the thickness, size, and location of the ~~physical insertion~~ insert by changing the z coordinate of elements surrounding the ~~insertion~~ insert and representing the change in the corneal elasticity caused by the of the first ~~physical~~ insertion of the insert in the cornea by means of a plurality of nonlinear spring elements having load deflection curves based upon the at least one material property value determined in step (d) and ~~physical insertion~~ insert thickness, each nonlinear spring element connecting a ~~physical insertion~~ insert affected node to an adjacent node, respectively, by shell modeling;

(f) using the finite element analysis model to compute at each of the nodes, new values of the patient specific x, y, z coordinates and therefrom, new strain relationships

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resulting from the ~~physical~~ insertion of the insert in the cornea at each of the nodes; and

(g) displaying the strain relationships at the nodes having the computed patient specific x, y, z coordinates to show the simulated resulting deformation of the cornea.

7. (currently amended) The computer-implemented method of claim 1 including establishing at least one vision objective for the patient's eye, said at least one vision objective being selected from the group consisting of visual acuity, duration of treatment, absence of side effects, low light vision, astigmatism, contrast and depth perception, and storing vision objective information in the storage device, wherein step (f) includes comparing the simulated deformation of the cornea with the vision objective information to determine if the ~~physical~~ insertion of the insert in the cornea results in the vision objective being met.

8. (currently amended) The computer-implemented method of claim 7 including, if the vision objective is not met, modifying [[a]] the first ~~physical~~ insertion of the insert in the cornea and/or adding a second ~~physical~~ insertion of another insert in the cornea in a finite

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element analysis model similar to the ~~physical~~ first insertion of the insert in the cornea, and repeating step (f) to determine if the vision objective is met.

9. (previously presented) The method of claim 8 wherein step (c) includes executing the finite element analysis model so as to homogenize the strain relationship of the surface of the patient's eye represented in the finite element analysis model.

10. (original) The computer-implemented method of claim 9 including measuring the thickness of various points of the cornea and/or sclera and assigning values of the measured thicknesses to each element of the finite element analysis model, respectively, before step (f).

11. (original) The computer-implemented method of claim 9 including modeling a thermal shrinkage of the cornea in the finite element analysis model by assigning at least one of reduced values of the thickness and a reduced value of the modulus of elasticity to elements corresponding to the thermally shrunk portion of the cornea, respectively.

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12. (currently amended) The computer-implemented method of claim 9 wherein the insert of the first ~~physical~~ insertion is a torous shaped insert.

13. (original) The computer-implemented method of claim 9 including assigning values of material constants of the eye, including Poisson's ratio, modulus of elasticity, and shear modulus, to each element of the finite element analysis model.

14. (currently amended) The computer-implemented method of claim 8 wherein the modifying includes executing a nonlinear programming computer program to determine how much to modify the number of ~~physical insertions~~ inserts, the shapes of the ~~physical insertions~~ inserts, the thickness of the ~~physical insertions~~ inserts and the locations of the ~~physical insertions~~ inserts.

15. (original) The computer-implemented method of claim 7 wherein establishing the at least one vision objective includes providing an initial set of surface curvatures for the cornea, the computer-implemented method including computing simulated post-operative curvatures from the new values of patient specific x, y, z coordinates

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computed in step (f) and comparing the simulated post-operative curvatures with the surface curvatures of the initial set to determine if the at least one vision objective is met.

16. (original) The method of claim 7 wherein each element of the finite element analysis model is an eight-node element, and wherein a boundary condition of the finite element analysis model is that a base portion of the finite element analysis model is stationary.

17. (original) The method of claim 8 including assigning substantially different measured values of strain to elements of cornea portions and sclera portions of the finite element analysis model.

18. (original) The computer-implemented method of claim 1 wherein step (c) includes executing a cubic spline computer program to obtain the reduced number of patient specific x , y , z coordinates according to an equation $z = ax^3 + bx^2 + cx + d$ which has been fit to the measured patient specific data points of step (a), x being a distance from an apex axis of the patient's eye.

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19. (original) The computer-implemented method of claim 8 including selecting at least one vision objective for each patient which produces a simulated multi-focal configuration of the cornea.

20. (currently amended) A computer-implemented method of simulating patient specific corneal deformation as a result of ~~a physical~~ an insertion of an insert in the cornea ~~[[on]]~~ of a patient's eye, comprising the steps of:

(a) measuring the topography of a portion of the patient's eye using a topography measuring device to produce patient specific x, y, z coordinates for a number of patient specific data points of a surface of the patient's eye;

(b) storing in a storage device associated with a computer system used for the computer-implemented method, a finite element analysis model of the patient's eye, the finite element analysis model including a predetermined number of nodes, the connectivities of which define a plurality of elements;

(c) operating a processing device operatively associated with the computer system to interpolate between and extrapolate beyond the patient specific data points to obtain a reduced number of patient specific x, y, z

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coordinates that correspond to nodes of the finite element analysis model, respectively, and assigning the x, y, z coordinates to the various nodes, respectively;

(d) determining a value representing intraocular pressure in the patient's eye and assigning a strain value to each element;

(e) representing ~~a physical~~ an insertion of an insert in the cornea, and thus a region of increased stiffness in the cornea, in the mathematical analysis model by assigning at least one of reduced values of the thickness and a reduced value of the modulus of elasticity to elements corresponding to the ~~physical~~ insertion of the insert in the cornea, respectively;

(f) using the finite element analysis model, computing new values of the patient specific x, y, z coordinates at each of the nodes to simulate deformation of the cornea resulting from the proposed ~~physical~~ insertion of the insert in the cornea; and

(g) operating the processing device to display the computed patient specific x, y, z coordinates to show the simulated deformation of the cornea.

21. (currently amended) A computer-implemented method of determining change of a cornea of a patient's eye as a

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result of ~~physical~~ an insertion of an insert in the cornea, the computer-implemented method including the steps of:

(a) storing in a storage device operatively associated with a computer system for implementing the computer-implemented method, a finite element analysis model of a patient's eye, the finite element analysis model including a number of nodes, the connectivities of which define a plurality of elements;

(b) applying a known external pressure to the patient's eye and then measuring the topography of a portion of the patient's eye using a topography measuring device to produce patient specific x, y, z coordinates for a number of patient specific data points of the pressure-deformed surface of the patient's eye and then remapping the topography by backcalculating the data;

(c) operating a processing device operatively associated with the computer system to interpolate between and extrapolate beyond the patient specific data points to obtain a reduced number of patient specific x, y, z coordinates that correspond to the nodes of the finite element analysis model, respectively, and assigning the reduced number of patient specific x, y, z coordinates to the various nodes respectively, and assigning the value of the external pressure to elements of the finite element

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analysis model corresponding to locations of the patient's eye to which the external pressure is applied in step (b);

(d) determining a value representing intraocular pressure in the patient's eye and assigning a strain value to each element;

(e) assigning initial values of the strain to each element, respectively, of the finite element analysis model;

(f) using the finite element analysis model, computing new values of the patient specific x, y, z coordinates at each of the nodes to simulate deformation of the cornea resulting from the external pressure and the intraocular pressure for the initial values of the strain;

(g) comparing the new values of the patient specific x, y, z coordinates computed in step (f) with the patient specific x, y, z coordinates recited in step (c);

(h) operating the processing device to modify values of the strain of the finite element analysis model, respectively, if the comparing of step (g) indicates a difference between the patient specific x, y, z coordinates obtained in step (c) and the patient specific x, y, z coordinates computed in step (f) exceeds a predetermined criteria;

(i) repeating steps (f) through (h) until final values

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of the strain are obtained;

(j) representing ~~a physical~~ an insertion of an insert in the cornea, and thus a region of increased stiffness in the cornea, in the mathematical analysis model by assigning at least one of reduced values of the thickness and a reduced value of the modulus of elasticity to elements corresponding to the ~~physical~~ insertion of the insert in the cornea, respectively;

(k) using the finite element analysis model, computing new values of the patient specific x, y, z coordinates at each of the nodes to simulate deformation of the cornea resulting from the proposed ~~physical~~ insertion of the insert in the cornea;

(l) comparing the simulated deformation of the cornea with at least one preestablished vision objective for the patient's eye, said at least one pre-established vision objective being selected from the group consisting of visual acuity, duration of treatment, absence of side effects, low light vision, astigmatism, contrast and depth perception, to determine if the ~~ablation~~ insertion of the insert in the cornea results in the vision objective being met; and

(m) if the vision objective is not met, modifying the proposed ~~physical~~ insertion of the insert in the cornea in

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the finite element analysis model and repeating steps (j) through (l) until the at least one pre-determined vision objective is met.

22. (currently amended) A computer-implemented method of simulating change of a cornea of patient specific patient's eye as a result of a proposed ~~physical~~ insertion of an insert ~~[[on]]~~ in the cornea, the computer implemented method including the steps of;

(a) storing in a storage device operatively associated with a computer system used for the computer-implemented method, a finite element analysis model of a patient's eye, the finite element analysis model including a number of nodes, the connectivities of which define a plurality of elements;

(b) applying a known external pressure to the patient's eye and then measuring the topography of a portion of the patient's eye under the influence of the externally applied pressure using a topography measuring device to produce patient specific x, y, z coordinates for a number of patient specific data points of the surface of the patient's eye and then remapping the topography by backcalculating the data;

(c) operating a processing device associated with the

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computer system to interpolate between and extrapolate beyond the patient specific data points to obtain a reduced number of patient specific x, y, z coordinates that correspond to the nodes of the finite element analysis model, respectively, and assigning the reduced number of patient specific x, y, z coordinates to the various nodes respectively, and assigning the value of the external pressure to elements of the finite element analysis model corresponding to locations of the patient's eye to which the external pressure is applied in step (b);

(d) determining a value representing intraocular pressure in the patient's eye and assigning a strain value to each element;

(e) assigning initial values of the strain to each element, respectively, of the finite element analysis model;

(f) using the finite element analysis model, computing new values of the patient specific x, y, z coordinates at each of the nodes to simulate deformation of the cornea resulting from the external pressure and the intraocular pressure for the initial values of the strain;

(g) comparing the new values of the patient specific x, y, z coordinates computed in step (f) with the patient specific x, y, z coordinates recited in step (c);

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(h) operating the processing device to modify values of the strain of the elements of the finite element analysis model respectively, if the comparing of step (g) indicates a difference between the patient specific x, y, z coordinates obtained in step (c) and the patient specific x, y, z coordinates computed in step (f) exceeds a predetermined criteria;

(i) repeating steps (f) through (h) until a final value of the strain is obtained;

(j) representing ~~the physical~~ an insertion of an insert in the cornea, and thus a region of increased stiffness in the cornea, in the finite element analysis model, by shell modeling, by representing the thickness of the ~~physical insertion~~ insert by changing the z coordinate of elements surrounding the ~~insertion~~ insert and representing the change in the corneal elasticity caused by a first ~~physical~~ insertion of an insert in the cornea by means of a plurality of nonlinear spring elements having load deflection curves based upon the at least one material property value determined in step (i) and ~~physical insertion~~ insert thickness, each of the plurality of nonlinear spring elements connecting ~~a physical insertion~~ bounding insert-bounding node to an adjacent node, respectively;

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(k) using the finite element analysis model, computing new values of the patient specific x, y, z coordinates at each of the nodes to simulate deformation of the cornea resulting from the ~~physical~~ insertion of the insert in the cornea and the intraocular pressure;

(l) comparing the simulated deformation of the cornea with at least one preestablished vision objective for the patient's eye to determine if the ~~physical~~ insertion of the insert in the cornea results in the at least one vision objective being met; and

(m) if the vision objective is not met, modifying the ~~physical~~ insertion of the insert in the cornea in the finite element analysis model and repeating steps (j) through (l) until the vision objective is met.